

REMARKS

Status of the claims

Claims 1-58 are pending and claims 1-3, 7-9, 32, 33, and 53-58 are under consideration in this application, claims 4-6, 10-31, and 34-52 having been withdrawn as allegedly being drawn to separate inventions. All the claims under consideration stand rejected. After entry of the amendments made herein, claims 1-3, 7-9, 32, 33, and 53-58 will be under consideration.

35 U.S.C. § 102 rejections

Claims 1-3, 7-9, 32-33, and 53-58 stand rejected as allegedly being anticipated: (1) under § 102(a) by Baker et al.; (2) under § 102(e) by Mitcham et al.; and (3) under § 102(e) by Fox et al.

Fox et al.

With regard to the rejection in view of Fox et al., the Examiner asserts that Fox et al. claims the same patentable invention as the instant claims (Office Action, page 3, lines 12-13). She further points out that, if Fox et al. and the instant application are not commonly owned, Fox et al. can only be overcome by establishing priority of invention through interference proceedings (Office Action, page 3, lines 15-16). Fox et al. and the instant application are not commonly owned.

In an unrelated application for which Examiner Roark was also the Examiner (U.S. Application Serial No. 09/649,108; the "'108 application"), there was an essentially identical situation involving a 35 U.S.C. § 102(e) rejection over a published U.S. Patent application reference. As in the present case, an Office Action asserted that the only way to overcome the rejection would be an interference proceeding. A strategy for responding to the rejection was agreed upon with Examiner Roark. Applicant understands that Examiner Roark is leaving the U.S. Patent and Trademark Office (USPTO) soon, likely before receipt by the USPTO of the instant Response. Thus, Applicants provide below, for the benefit of Examiner Roark's successor, a statement of the strategy agreed to in the '108 application.

After consultation with Supervisory Examiners Amy Nelson and Anthony Caputa and Examiner Roark, it was concluded that the appropriate strategy for Applicant in the '108 application should be to: (a) address in a Response any outstanding issues other than the "interference-type" 35 U.S.C. §102(e) rejection; and (b) request in the Response abeyance of the 35 U.S.C. §102(e) rejection until the published U.S. Patent application reference issued as a U.S. Patent. Examiner Nelson indicated that, if no other outstanding issues remained in the application, the request for abeyance would be granted.

Thus, consistent with the above-described strategy, Applicant addresses below the rejections for anticipation in view of Baker et al. and Mitcham et al. and requests that the 35 U.S.C. §102(e) rejection in view of Fox et al. (a published U.S. Patent application) be held in abeyance until Fox et al. issues as a U.S. Patent. Applicant makes no admission as to whether Fox et al. claims the same invention specified by the instant claims.

Baker et al. and Mitcham et al.

First, the Examiner indicates that it is not clear to what country the term "this country" in the Applicant's declaration submitted with the Response of August 5, 2003, refers. Applicant resubmits the declaration herewith (as Exhibit A) with term "this country" replaced with "the United States".

The Examiner next asserts that the "instant claims are drawn to a genus of nucleic acids, whereas the evidence provided in the Declaration is limited to a single nucleic acid sequence. The scope of the declaration is thus not commensurate with the scope of the claims." Applicant disagrees with this position and respectfully submits that, in view of guidance provided by the MPEP on what evidence need be provided in a 37 C.F.R. 1.131 declaration ("131 declaration") declaration in order to overcome a rejection based on a reference that discloses a claimed genus (see below), the showing (by Exhibit A) of Applicant's possession of the nucleic acid sequence with SEQ ID NO:6 is sufficient to overcome the rejection in view of disclosure of the claimed genus by the cited references. The claimed genus in this case is the genus of: (a) nucleic acid sequences that hybridize, after a wash at 50°C to 65°C in a buffer containing 0.2 x SSC and 0.1%

SDS (i.e., highly stringent conditions), to the complement of the nucleotide sequence set forth in SEQ ID NO:6); or (b) the complements of the nucleic acids.

The MPEP states that, with respect to references that disclose a claimed genus, "a showing of completion of a single species within the genus is sufficient to antedate the reference . . . under 37 CFR 1.131." MPEP § 715.03, citing *Ex parte Biesecker*, 144 USPQ 129 (Bd. App. 1964) While indicating that this may not be the case "where predictability is in question," the MPEP states generally that

[i]t is not necessary for the affidavit evidence to show that the applicant viewed his or her invention as encompassing more than the species he or she actually made. The test is whether the facts set out in the affidavit are such as would persuade one skilled in the art that the applicant possessed so much of the invention as is shown in the reference. MPEP § 715.03, citing *In re Schaub*, 537 F.2d 509, 190 USPQ 324 (CCPA 1976)

It thus appears that the issue in the instant situation is whether, in possessing the sequence identified by SEQ ID NO:6, Applicants possessed as much of the presently claimed invention as is shown in the reference, i.e., nucleic acid sequences that hybridize, after a wash at 50°C to 65°C in a buffer containing 0.2 x SSC and 0.1% SDS (i.e., highly stringent conditions), to the complement of the nucleotide sequence set forth in SEQ ID NO:6). Example 9 of the "Guidelines for the Examination of Patent Applications Under the 35 U.S.C. §112, ¶ 1, Written Description Requirement" (the "Guidelines") is informative in this regard. Example 9 in the Guidelines indicates that the disclosure of a single nucleic acid species (designated SEQ ID NO: 1 in the example) by an application is sufficient to show that the "applicant was in possession of the claimed invention" as defined by a claim specifying: "An isolated nucleic acid that specifically hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO:1."

In light of these considerations, Applicant submits that possession of the sequence shown in the enclosed declaration was sufficient to show he was in possession of the genus recited in claim 1 and hence was also sufficient to also antedate both Baker et al. and Mitcham et al. with respect to this genus.

The Examiner also points out that the two references disclose vectors (including expression vectors) containing the DNA sequence at issue, host cells comprising the vectors, and methods of producing the polypeptide encoded by the DNA sequence (Office Action, page 3, lines 28-33, and page 4, lines 9-15), all of which are specified by the instant claims but are not disclosed by the enclosed declaration. In this regard, the MPEP is also informative and states, for example, that

[e]ven if applicant's 37 CFR 1.131 affidavit is not fully commensurate with the rejected claim, the applicant can overcome the rejection by showing that the differences between the claimed invention and the showing under 37 CFR 1.131 would have been obvious to one of ordinary skill in the art, prior to the effective date of the reference(s) or the activity. Such evidence is sufficient because applicant's possession of what is shown carries with it possession of variations and adaptations which would have been obvious, at the time, to one of ordinary skill in the art. However, the affidavit or declaration showing must still establish possession of the invention (i.e., the basic inventive concept). MPEP § 715.02, citing *In re Spiller*, 500 F.2d 1170, 182 USPQ 614 (CCPA 1974)

With respect to the above teaching of the MPEP, Applicant respectfully submits that, as shown by the enclosed declaration, prior to the effective date of Mitcham et al. and Baker et al., Applicant was in possession of the "basic inventive concept" (i.e., SEQ ID NO:6). Applicant submits, moreover, that one of ordinary skill in the art being in possession of SEQ ID NO:6 would have considered vectors, generally, containing the sequence with SEQ ID NO:6 (or other sequences within the scope of claim 1), host cells, generally, containing the vectors, and methods, generally, of producing the protein encoded by SEQ ID NO:6 to be obvious "adaptations" of the basic inventive concept. This contention is supported by the inclusion of such adaptations in both Baker et al. and Mitcham et al. in which the work of the relevant inventors provided no more than the discovery of the nucleotide sequences of SEQ ID NO:391 and DNA encoding the PRO1291 polypeptide, respectively.

In light of the above considerations, Applicant requests that the rejections under 35 U.S.C. § 102 in view of Baker et al. and Mitcham et al. be withdrawn.

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CONCLUSIONS

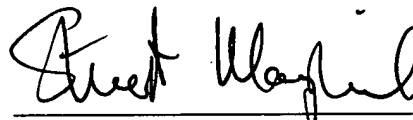
Applicant submits that the pending claims patentably define the invention. Applicant requests that the Examiner reconsider the rejections set forth in the Office Action, and permit the pending claims to pass to allowance.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's undersigned representative can be reached at the telephone number listed below.

Enclosed is a Request for an Automatic Extension of Time and check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No. 07039-219001.

Respectfully submitted,

Date: 3/26/04



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